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IS 4978 (1985): Forceps, Eye, Fixation (Toothed) [MHD 5: Ophthalmic Instruments and Appliances]



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Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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IS : 4978 - 1985

Indian Standard
SPECIFICATION FOR
FORCEPS, EYE, FIXATION (TOOTHED)
(*First Revision*)

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MANAK BHAVAN, 9 BHADUR SHAH ZAFAR MARG
NEW DELHI 110002

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Indian Standard

SPECIFICATION FOR FORCEPS, EYE, FIXATION (TOOTHED) (First Revision)

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Indian Standard
SPECIFICATION FOR
FORCEPS, EYE, FIXATION (TOOTHED)
(First Revision)

0. FOREWORD

0.1 This Indian Standard (First Revision) was adopted by the Indian Standards Institution on 25 November 1985, after the draft finalized by the Eye Surgery Instruments Sectional Committee had been approved by the Consumer Products & Medical Instruments Division Council.

0.2 This standard was first published in 1968. The present revision has been taken up to include certain modifications in order to bring the specification in line with the modern manufacturing practices. In the revised standard the non-functional dimensions have been rounded off. The tolerance for the functional dimensions have been modified keeping in view the present manufacturing technique. A clause on sampling and inspection has been added. The test methods have been brought in line with the test methods covered in other similar standards of eye surgery instruments.

0.3 For the purpose of deciding whether a particular requirement of the standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard covers requirements for toothed fixation forceps, used in eye surgery.

2. MATERIAL

2.1 The material of forceps shall be stainless steel conforming to Designation 30 Cr 13 of IS : 6603-1972†.

*Rules for rounding off numerical values (revised).

†Specification for stainless steel bars and flats.

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2.2 Rivets, block for block joint, check pin and guide pin shall be of stainless steel used for the arms.

3. SHAPE AND DIMENSIONS}

3.1 The shape and dimensions shall be as shown in Fig. 1 to 4.

3.2 Joints — The joints shall be of semi-block joint conforming to IS : 3642-1978*.

3.3 Teeth — The teeth of the forceps shown in Fig. 1 and 2 shall conform to Section 4 of IS : 3642-1978* combinations of teeth being 1 in 2 and 2 in 3 respectively. The teeth shall be pointed and to the dimensions shown in Fig. 1 and 2.

3.3.1 The teeth of the forceps shown in Fig. 3 and 4 shall have their shapes and dimensions as indicated thereon. The performance, workmanship and finish aspects covered in Section 4 of IS : 3642-1978* shall be applicable to these types of teeth also. The combination of teeth shall be 2 in 3 and 3 in 4 respectively.

3.4 A deviation of ± 1.5 percent shall be allowed on all dimensions.

4. WORKMANSHIP AND FINISH

4.1 The arms of the forceps shall be symmetrical and balanced.

4.2 The jaws shall close and open with even movement, the teeth so matching as to register properly without over-riding, sticking or locking. When the teeth get fully engaged with no material held in between them, the guide pin shall not project beyond the outer surface of the guide hole. The guide pin shall, in no case, stick in the hole.

4.3 The arms shall be free from burrs, pits, cracks, seams, scales, flaws and other surface defects.

4.4 All edges of the forceps, except the teeth shall be smooth and even and shall not be sharp.

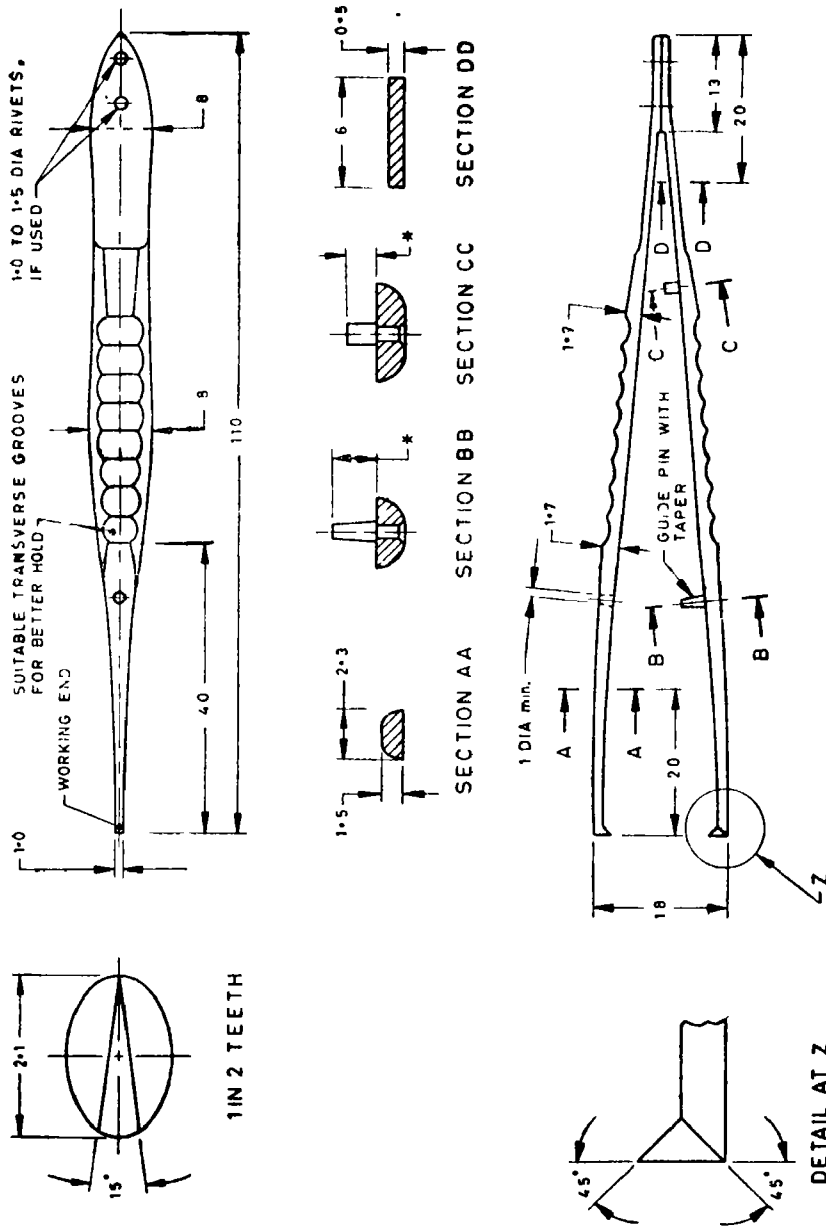
4.5 The faces of the arms shall be passivated and highly polished.

4.6 The teeth shall be clean and bright.

5. HARDNESS

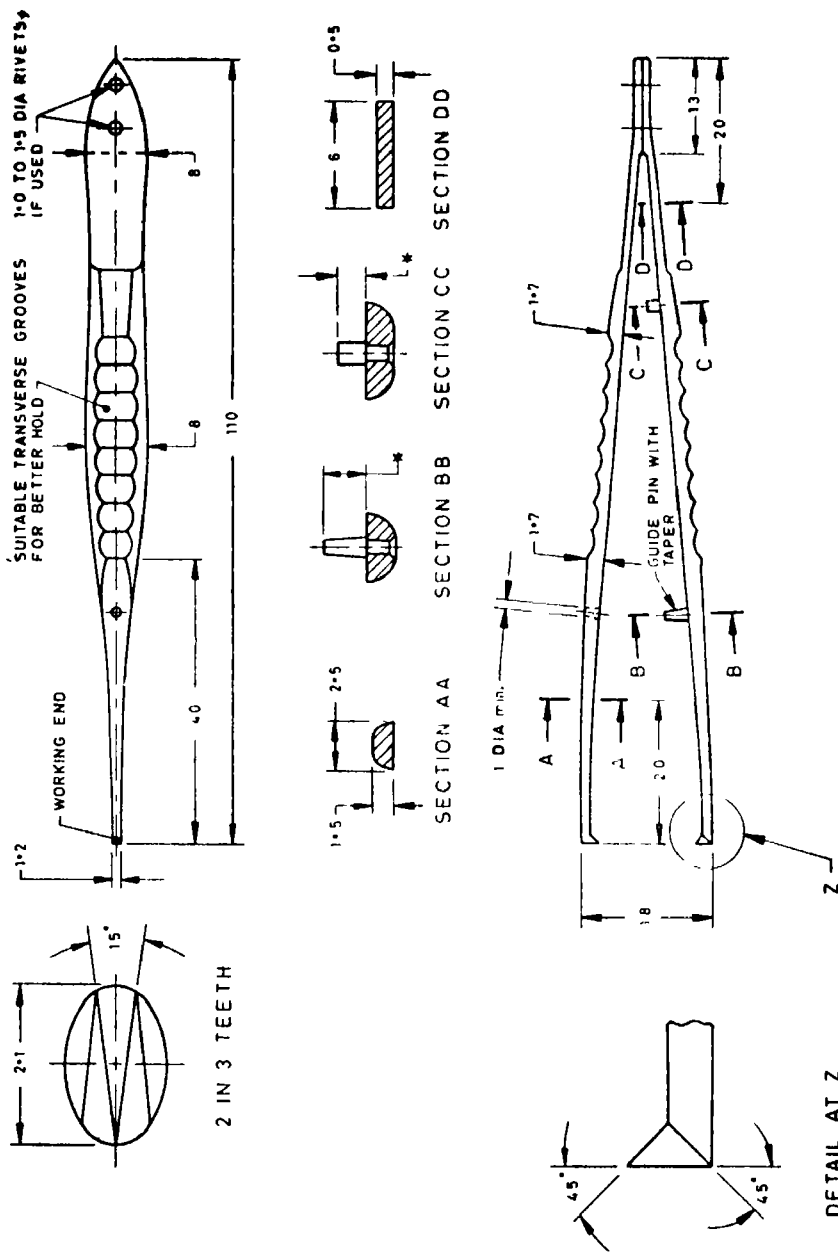
5.1 The forceps shall be suitably hardened and tempered to give a hardness of 380 to 440 HV.

*General requirements for surgical instruments (*first revision*).



*Length of pins to suit the requirements of 4.2.
All dimensions in millimetres.

FIG. 1 FORCEPS, EYE, FIXATION, TOOTHED



* Length of pins to suit the requirements of 4.2.
All dimensions in millimetres.

FIG. 2 FORCEPS, EYE, FIXATION, TOOTHED

*Length of pins to suit the requirements of 4.2.

All dimensions in millimetres.

FIG. 4 FORCEPS, EYE, FIXATION, CROSSING TYPE TEETH

6. TESTS

6.1 Load Closure — The load to make the tips of the forceps just touch, shall be 225 ± 20 g. This load shall be applied at the end of the finger grooves proximal to the tip of the forceps.

6.2 Test for Engagement of Teeth — A latex sheet of 0.05 mm thickness conforming to IS : 5430-1981* shall be stretched over the tip of the fingers. The stretched latex sheet shall then be gripped by the teeth of the forceps and pulled to a distance of 6 mm. The forceps shall hold the latex sheet firmly without any tendency to slipping and the latex sheet shall not be punctured or damaged.

6.3 Flexibility — The arms of the forceps after maximal closure by manual compression shall not take a permanent set, and the teeth shall continue to engage and disengage accurately and properly.

6.3.1 The joint end of the forceps shall be fixed in a vice so that the riveted or welded portion of the joint is gripped firmly. By the application of force at the tip of the arm, one arm of the forceps shall be deflected in a plane at right angles to the plane of the arm by 30 mm, measured at the tip.

6.3.1.1 On release of force, no permanent set shall be observed. The test shall be repeated on the other arm.

6.4 Corrosion Resistance — The forceps shall be tested for corrosion resistance in accordance with IS : 7531-1975†. The forceps shall not show any sign of corrosion after the test.

7. SAMPLING AND CRITERIA FOR CONFORMITY

7.1 A suitable sampling scheme and criteria for acceptance is given in Appendix A.

8. MARKING

8.1 The forceps shall be clearly and indelibly marked with the manufacturer's name, initials or recognized trade-mark and the word 'stainless steel' or letters 'SS'.

8.1.1 The forceps may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

*Specification for ammonia preserved concentrated natural rubber latex.

†Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments.

9. PACKING

9.1 The forceps shall be wrapped individually in moisture-proof paper or polyethylene bag. They shall be packed in a manner so as to avoid contact with one another. The teeth shall be suitably protected.

APPENDIX A

(Clause 7.1)

SAMPLING AND CRITERIA FOR CONFORMITY FOR FORCEPS

A-1. Lot — In any consignment, all the forceps produced from the same material and same shape and dimensions under similar conditions, shall constitute a lot.

A-2. The number of forceps to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

TABLE 1 SCALE OF SAMPLING

LOT SIZE	SAMPLE SIZE
(1)	(2)
Up to 15	2
16 „ 50	3
51 „ 150	5
151 and above	8

A-2.1 These forceps shall be selected from the lot at random and in order to ensure the randomness of selection, procedures given in IS : 4905-1968* may be followed.

A-3. Number of Tests and Criteria for Conformity — All the forceps selected at random in accordance with col 1 and 2 of Table 1 shall be tested for hardness, workmanship and finish, load closure, engagement of teeth, flexibility, and corrosion resistance. The lot shall be considered as conforming to these requirements if none of the forceps in the sample is found to be defective in any of these tests.

*Methods for random sampling.

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*Methods for random sampling.



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